

Attorney Docket No.: 6169.200-US  
Serial No.: 09/800,541  
Filed: 03/07/2001  
Via Facsimile No.: 571-273-8300

RECEIVED  
CENTRAL FAX CENTER  
DEC 22 2006

### REMARKS

Claims 26, 28-29, 36, 43-50, and 73-80 will be pending in this application upon entry of the present amendment. Support for the amendments to the claims can be found in the specification. Specific support for the amendments to claim 1 can be found on page 12 (formula II), page 22 (formula I), and page 8 (inherent absence of insulin). No new matter would be added upon entry of the present amendment.

### REJECTION OF THE CLAIMS UNDER 35 USC 112

The rejection of claims 26-29 and 36-72 (now 26, 28-29, 36, 43-50, and 73-80) under §112, 1<sup>st</sup> paragraph, has been obviated by appropriate amendment.

The claims have been limited to methods of lowering one or more serum lipids, wherein the lipids are selected from triglycerides and free fatty acids. The Office Action states in the paragraph bridging pages 2-3 that the above-identified application is enabled for the method of lowering these three lipids. Withdrawal of this rejection is respectfully requested.

The rejection of claims 26, 27, 29, 36, 37, 40, 42, 44-49, 52, 54-59, 62, 64-69, 72-73, and 76 (now 26, 29, 36, 43-49, 73, and 76) under §112, 1<sup>st</sup> paragraph, has been obviated by appropriate amendment.

This rejection pertains to whether applicants had possession of the claimed invention in view of the terms analogue and derivative. The presently claimed invention now recites specific structures for the claimed analogues and derivatives. These structures, which are based on figures I and II, were present in the application and have now been incorporated into the present claims. In view of the definitions of analogue and derivative now presently

Attorney Docket No.: 6169.200-US  
Serial No.: 09/800,541  
Filed: 03/07/2001  
Via Facsimile No.: 571-273-8300

recited, Applicants submit that the claims show that Applicants had possession of the claimed invention.

The rejection of claims 44-49, 52, 54-59, 62, 64-69, 72-73, and 76 (now 44-49, 73, and 76) under §112, 2<sup>nd</sup> paragraph, has been obviated by appropriate amendment.

This rejection pertains to whether Applicants have particularly pointed out and distinctly claimed the invention. As noted above, the definitions of analogue and derivative have now been added to the claims. In view of this, Applicants respectfully submit that the subject matter of the claims is particularly pointed out and distinctly claimed. Withdrawal of this rejection is respectfully requested.

#### **REJECTION OF THE CLAIMS UNDER 35 U.S.C. 102(b)**

The rejection of claims 26-29, 36-42, 44, 46, 48, 51-52, 54, 56, 58, 61-62, 64, 66, 68, 71-74, and 76 (now 26, 28-29, 36, 44, 46, 48, 73, and 76) under 35 U.S.C. 102(b) over Beeley (WO98/30231) has been obviated by appropriate amendment.

Beeley relates to the use of exendin-3 or exendin-4, neither of which are recited in the present claims. Withdrawal of this rejection is respectfully requested.

The rejection of claims 26-27, 29, 36-37, 39-40, 42-43, 46, 48, 52-54, 56, 58, 62-64, 66, 68, 72-73, and 76 (now 26, 29, 36, 43, 46, 48, 73, and 76) under 35 U.S.C. 102(b) over Juntti-Berggren has been obviated by appropriate amendment.

Juntti-Berggren relates only to the dual therapy of insulin (intensive treatment) and GLP-1(7-36)amide. The study described in Juntti-Berggren administered insulin for 7 days, then insulin and GLP-1(7-36)amide for 5 days, and finally GLP-1(7-36)amide for the last two days of the study (during insulin washout). Juntti-Berggren reported that this treatment had no effect on the levels of LDL and HDL cholestetrol. In contrast, the presently claimed

Attorney Docket No.: 6169.200-US  
Serial No.: 09/800,541  
Filed: 03/07/2001  
Via Facsimile No.: 571-273-8300

invention recites a method of lowering triglycerides and free fatty acids by administering one of the recited GLP-1 compounds to a patient who is not receiving insulin treatment. Since Juntti-Berggen is only limited to insulin treated patients and describes the effects of their dual therapy protocol on LDL and HDL cholesterol, Applicant submits that the present claims cannot be anticipated. Withdrawal of this rejection is respectfully traversed.

**REJECTION OF THE CLAIMS UNDER 35 U.S.C. 103(a)**

The rejection of claims 26-29, 36-42, 44, 46, 48, 51-52, 54, 56, 58, 61-62, 64, 66, 68, 71-74, and 76 (now 26, 28-29, 36, 44, 46, 48, 73, and 76) under 35 U.S.C. 103(a) over Beeley (WO98/30231) has been obviated by appropriate amendment.

As noted above, Beeley relates to the use of exendin-3 or exendin-4, neither of which are recited in the present claims. Withdrawal of this rejection is respectfully requested.

The rejection of claims 26-29, 36-42, 44, 46, 48, 51-52, 54, 56, 58, 61-62, 64, 66, 68, 71-74, and 76 (now 26, 28-29, 36, 44, 46, 48, 73, and 76) under 35 U.S.C. 103(a) over Beeley (WO98/30231) in view of Juntti-Berggen and Knudsen has been obviated by appropriate amendment.

Applicant submits that neither Juntti-Berggen nor Knudsen can cure the deficiencies of Beeley. Beeley relates to the use of exendin-3 or exendin-4, neither of which are recited in the present claims. Juntti-Berggen relates to dual therapy of insulin and GLP-1 (7-36) amide, which is not part of the present claims, and Juntti-Berggen reported that this treatment had no effect on the levels of LDL and HDL cholesterol. Knudsen merely relates to known GLP-1 analogues. Thus, the combination of these three references doesn't get one to the presently claimed method for lowering levels of triglycerides and/or free fatty acids by administering to a patient a GLP-1 agonist, as defined herein, wherein the treated patient is not receiving

Attorney Docket No.: 6169.200-US  
Serial No.: 09/800,541  
Filed: 03/07/2001  
Via Facsimile No.: 571-273-8300

insulin treatment. Withdrawal of this rejection is respectfully requested.

### **OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION**

The obviousness-type double patenting rejection of claims 26-29, 36-42, 44-50, 52, 54-60, 62, 64-70, 72-73, and 76 (now 26, 28-29, 36, 44-50, 73, and 76) over claims 39-40 of US 6,268,343 (US '343) in view of Beeley has been obviated by appropriate amendment.

Claims 39-40 of US '343 recite a method of treating diabetes or obesity, respectively, comprising administering a GLP-1 derivative of claim 1. US '343 is completely silent regarding a method of lowering serum levels of triglycerides and/or free fatty acids. The Office Action states that Beeley cures the deficiency of US '343 by describing a method of lowering plasma lipids etc. by administering an exendin agonist. The problem is, Beeley relates to exendins, US '343 does not. Another problem is that Juntti-Berggen relates to dual therapy with insulin and GLP-1 (7-36) amide, which is not part of the present claims, and Juntti-Berggen reported that this treatment had no effect on the levels of LDL and HDL cholesterol. In light of the above, there would be no reason to think that the derivatives of US '343 would be useful in lowering triglycerides or free fatty acids in view of the effects of exendins described in Beeley. Withdrawal of this rejection is respectfully requested.

The obviousness-type double patenting rejection of claims 26-29, 36-42, 44-50, 52, 54-60, 62, 64-70, 72-73, and 76 (now 26, 28-29, 36, 44-50, 73, and 76) over claims 19-20 US 6,458,924 (US '924) in view of Beeley has been obviated by appropriate amendment.

Claims 19-20 of US '924 recite a method of treating diabetes or obesity, respectively, comprising administering a GLP-1 derivative of claim 1. US '924 is completely silent regarding a method of lowering serum levels of triglycerides and free fatty acids. The Office Action states that since Beeley cures the deficiency of US '924 by describing a method of

Attorney Docket No.: 6169.200-US  
Serial No.: 09/800,541  
Filed: 03/07/2001  
Via Facsimile No.: 571-273-8300

lowering plasma lipids etc. by administering an exendin agonist. The problem is, Beeley relates to exendins, US '924 does not. Another problem is that Juntti-Berggen relates to dual therapy of insulin and GLP-1 (7-36) amide, which is not part of the present claims, and Juntti-Berggen reported that this treatment had no effect on the levels of LDL and HDL cholesterol. In light of the above, there would be no reason to think that the derivatives of US '924 would be useful in lowering triglycerides or free fatty acids in view of the effects of exendins described in Beeley. Withdrawal of this rejection is respectfully requested.


#### **CLAIM OBJECTIONS**

The objection to Claim 74 has been obviated by appropriate amendment. Withdrawal of this rejection is respectfully requested.

It is believed that the claims as presented are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

Date: December 22, 2006

  
Richard W. Bork, Reg. No. 36,459  
Novo Nordisk, Inc.  
100 College Road West  
Princeton, NJ 08540  
(609) 987-5800

Use the following customer number for all correspondence regarding this application.

23650

PATENT TRADEMARK OFFICE